

REMARKS

Claim 1 has been amended to address the only outstanding grounds for rejection.

Claim 63 has been canceled as redundant with the requirement that the protein and polysaccharide be conjugated. The phrase "is characteristic of a" has been replaced by "is an antigen of a" for clarity and in response to the rejection under 35 U.S.C. § 112, paragraph 2. No new matter has been added and entry of the amendment is respectfully requested.

Formal Matters

First, applicants note that the interview summary of a telephonic interview held 24 June 2003 between Examiners Ford, Smith, and a colleague of the undersigned, Carolyn Favorito, requires that the applicants supply a summary of the content of the interview. Since the interview is summarized by the Examiner, perhaps the omission to check the box indicating it not necessary for applicant to provide a separate record was inadvertent. In any event, a summary is provided in the context of the present response. Applicants summarize the contents of the interview as follows:

No agreement was reached. Applicants stated that the meaning of the phrase "characteristic of" a pathogenic microorganism was meant to state that the polysaccharide was "derived from" that organism. Applicants representative did not, however, state that the "essence of" the invention was an immuno composition where the protein and polysaccharide component (wherein the protein is rARU) are not conjugated. Rather, applicants representative stated that the claims as then drawn, were not limited to conjugated protein and polysaccharide.

It is believed that the foregoing is an adequate summary of the interview.

Applicants appreciate the withdrawal of the rejections previously made over the art.

The Rejection Under 35 U.S.C. § 112, First Paragraph

All claims were rejected under this section. However, it is believed that the claims as amended are free of this rejection. The Office acknowledges that the specification is enabling for the claimed compositions when the polysaccharide component is conjugated to the rARU of *C. difficile* and the polysaccharide component is characteristic of (or derived from) a pathogenic microorganism other than *C. difficile*. It should be noted that claim 63, presumably unintentionally included in this rejection, is indeed limited to conjugated forms of the composition.

In any event, claim 1 has been amended, in order to expedite prosecution, to limit the claimed subject matter to compositions where the polysaccharide and protein are conjugated, a scope which is acknowledged as enabled by the Office. It is believed that the amendment to the claims renders this basis for rejection moot.

The Rejection Under 35 U.S.C. § 112, Paragraph 2

The term “characteristic of” in claim 1 was objected to as unclear. This has been changed to “an antigen.” It is believed this amendment obviates the rejection under this statutory section.

Rejoinder

Rejoinder of claims 64-66 is also requested. Since claims 64-66 are each directed to a single method to use compositions that are claimed in allowable claims, it is believed proper to rejoin these claims in the present application. This is in accordance with MPEP § 821.04 which states that if applicant elects claims directed to a product, and the product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

CONCLUSION

The claims have been limited to a preferred embodiment which is acknowledged by the Office to be enabled by the specification, thus disposing of the only substantive ground for rejection. The objected-to term in claim 1 has also been replaced in order to obviate a rejection for indefiniteness. It is therefore believed that claims 1, 3, 6, 13-15, 19-20, 23-26, 28-33, 36-39 and 62-66 are clearly in a position for allowance and passage of these claims to issue is respectfully requested.

Should any matters remain to be resolved, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 420522000100.

Respectfully submitted,

Dated: December 8, 2003

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